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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/792,178

03/03/2004

David E. Francischelli

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EXAMINER

JOHNSON III, HENRY M

ART UNIT

PAPER NUMBER

3769

NOTIFICATION DATE

DELIVERY MODE

10/07/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/792,178	Applicant(s) FRANCISCHELLI ET AL.	
	Examiner Henry M. Johnson, III	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☐ Claim(s) 25-33 and 80 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 80 is/are allowed.
- 7) ☒ Claim(s) 25-33 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed September 23, 2011 with respect to 35 U.S.C. § 112 rejections have been fully considered and are persuasive. These rejections have been withdrawn.

Applicant's arguments filed September 23, 2011 with respect to 35 U.S.C. § 103 rejections have been fully considered but they are not persuasive. Applicant argues that Nardella does not teach detecting a vibration during a phase-transition but prior to boiling. Nardella is concerned with avoiding damage to tissue using vibration sensing. A skilled artisan would clearly be aware of the various vibrations associated with and preceding a boiling point rendering these vibration points valid points at which to control the ablation energy.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,733,281 to Nardella. Nardella discloses a method of tissue ablation comprising positioning an electrode (energy delivering electrode; Col. 4, lines 20-25, positioning is inherent for an ablation operation), supplying electrical power

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(electrosurgical energy; Col. 6, lines 54-55), sensing with a sensor (acoustical detection element; Col. 2, lines 46-49) the vibration of the tissue and reducing/halting ("regulating", patented claim 3; power regulation element; col. 8, lines 57-60) power when the vibration reaches a given value. The acoustic detection element may be a piezoelectric ceramic crystal (Col. 7, line 35) or a microphone (Col 3, line 4). Nardella teaches a feedback system that includes an acoustical detection element coupled to the surgical tool and the pulse regulation element for acoustically detecting the effects of energy on tissue, such as the generation of steam created during the heating process. The acoustical detection element preferably generates an acoustic output signal, and the power regulation element preferably regulates the application of power to the energy-delivering electrode in response to either the derivative output signal or the acoustic output signal (Col. 2, lines 46-51).

Nardella, however, does not specifically disclose reducing power in response to a vibration during phase-transition, prior to boiling. Nardella is concerned with the destructive effects of steam during tissue ablation and associates steam and "pops" with steam buildup that may lead cells to explode (Col. 1, lines 25-48). Nardella teaches adjusting the acoustic (vibration) feedback to regulate the relative levels of steam to within a selected range, and preferably below that level that may cause permanent and/or unwanted damage to the tissue (Col. 6, lines 42-46). It is the examiner's position that one of skill in the art, aware of such serious issues, would associate boiling, phase-transition and steam pops as indicative of excessive energy. Nardella specifically teaches that the term "acoustic" is intended to include any vibratory disturbance of any

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frequency in a selected fluid, such as air, and includes sonic and ultrasonic waves (Col. 2, lines 46-59).

Regarding claim 27, Nardella incorporates by reference in Col. 9, line 56, Nardella (5,334,193), which discloses impedance feedback control of fluid delivery to treated tissue (see '193 Abstract).

Regarding claims 29 and 30, Nardella discloses an output device (Analyzer, Fig. 2, # 130) and an indicator signal (Fig. 2, # 132, signal to RF generator).

Regarding claim 32, PVDF is a piezoelectric polymer (Col. 7, line 36).

Regarding claim 33, sensor (Fig. 2, # 20) is integrated with the electrode (Fig. 2, # 12).

Allowable Subject Matter

Claim 80 is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571)272-4768. The examiner can normally be reached on M-F, 6 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam C. Yao can be reached on 571.272.1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Henry M. Johnson, III/
Primary Examiner, Art Unit 3769

October 1, 2011